DEC - 9 2004

K042318

Revised Summary

In Vitro Diagnostic Devices: Aalto Scientific, Ltd. 510(k) Submissions Summary Form

Name:	Aalto Scientific, Ltd.
Address:	1959 Kellogg Ave, Carlsbad, CA 92008
Telephone:	760 – 431-7922
Fax Number:	760 – 431-6942
Contact Person:	Alan Vekich Ext: 120
Establishment Registration Number:	2022832

Identification of the Device

Device Name:	Audit™ MicroCV™ General Chemistry Linearity Set
Proprietary/Trade name:	Audit™ MicroCV™ Linearity Set
Common Name:	General Chemistry Linearity
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR § 862.1660
Panel:	75
Product Code:	JJY

Identification of the Predicate Device

Predicate Device Name:	Validate Chem 10 Calibration Verification Test Set
Manufacturer:	Maine Standards Company
510(k) Number or Clearance Information:	K023410
Predicate Device Labeling:	

Description of the Device and reason for the submission

The Device is a QC material that will be used to determine the linearity of clinical chemistry assays as defined by CLIA-88 in Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003.

OCT 0 1 2004

Intended Use(s) and Indication(s) for Use of the subject device

Audit™ Micro*CV*™ General Chemistry Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Magnesium, ~~Osmolality~~, Phosphorus, Potassium, Sodium, Total Protein, Lipase, Lactate, Triglycerides and Uric Acid. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments.

This product may also be used as unassayed quality control material for these same analytes and may be used for proficiency testing in interlaboratory surveys. In addition, this product may also be used to perform CLIA directed calibration verification for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations.

Substantial Equivalence

Name:	Validate® Chem 10 Calibration Verification Test Set	Audit™ Micro*CV*™ General Chemistry Linearity Set
510(k) Number:	K023410	K042318
Intended Use:	Validate Chem 10 Calibration Verification Test Set solutions are intended for *in vitro* diagnostic use in verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	Audit™ Micro*CV*™ General Chemistry Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures. This product may also be used as unassayed quality control material for these same analytes and may be used for proficiency testing in interlaboratory surveys. In addition, this product may also be used to perform CLIA directed calibration verification for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations.
Stability Claims:	Stable until the expiration date printed on the bottle and storage container when stored at –10 to -20° C and handled according to instructions.	Stored at 2-8° C and will remain stable in the unopened vial for twelve months from the date of manufacture. After opening, the contents should be reconstituted immediately and used according

		to the instrument manufacturer's instructions. After reconstitution material is stable 24 hours.
Constituents:	Alkaline phosphates (ALP) Alanine aminotransferase (ALT) Amylase (AMY) Aspartate aminotransferase (AST) Creatine kinase (CK) χ-glutamyl transferase (GGT) Lactate dehydrogenase (LD) Lipase (LIP) Bilirubin, total	Alkaline phosphates (ALP) Alanine aminotransferase (ALT) Amylase (AMY) Aspartate aminotransferase (AST) Creatine kinase (CK) χ-glutamyl transferase (GGT) Lactate dehydrogenase (LD) Lipase (LIP) Bilirubin, total Acid Phosphatase, Total Albumin Bilirubin, Conjugated Calcium Chloride Lactate Cholesterol Carbon dioxide Creatinine Glucose HDL Cholesterol Iron, Total LDL Cholesterol Magnesium [redacted] Phosphorus Potassium Sodium Total Protein Triglycerides Urea (BUN) Uric Acid
Levels Available:	Five	Five
Contents:	10 x 5mls	5 x 5 mls

Technological Characteristics of the Device

The five levels QC material is to be assayed as an unknown for the determination of linearity.

Performance Characteristics and Data[1]

Specific Performance Characteristics and Data

Method Comparison - a method comparison for each sample or matrix claimed for analysis, e.g., whole blood, capillary whole blood, serum, plasma, urine, etc.

Matrix:

1. The base matrix is mixture of two animal sera: Bovine serum and Normal Processed Human Serum that has had the lipids removed.

2. NaCl, LiCl, Lactic Acid, BUN (Urea), $CaCl_2$, Creatinine, Dextose, $MgCl_2$, $NaHPO_4$, Uric Acid, KCl, iron, Na Acetate, Conjugate Bilirubin, Bilirubin, are ACS or Reagent Grade Commercially available chemicals. Used as an analyte adjustor.

3. Pyridoxal-5-Phosphate is an ACS or Reagent Grade Commercially available chemicals and used either as weighed crystal or dissolved in DI water and measured out as a liquid. Used as a stabilizer.

4. LD, AST/SGOT, ALT/SGPT, CK, GGT, Amylase, Lipase, Alkaline Phosphatase, and Acid Phosphatase are plant or animal derived material from approved vendors. The Vendors supply a COA and Aalto Scientific, Ltd.'s QA department confirms the claims.

5. Sucrose and Sorbitol are ACS or Reagent Grade Commercially available chemicals and used as a Freeze/Dry bulking agent and preservative.

The QC materials and methods used in the manufacturing of the General Chemistry Linearity Set. Level A though E where Class A type general chemistry equipment (such as graduated cylinders) and calibrated balances. Testing materials where the reagents, calibrators and controls that were obtained from the respected manufacturers.

Precision/Reproducibility: N/A
Linearity/assay reportable range: N/A

Manufacturing:

The Linearity set is made according to NCCLS protocol #EP6-A for a five level linearity set. The dilution schemes can be found in Appendix A for a five level sample with equally spaced concentrations. Just like a Proficiency Sample Set where the actual concentrations are not important for the purposes of assessing linearity as long as dilutions are proportional. The linear range will be defined by the highest and lowest measured concentrations where the response is linear. The manufacturing targets for each analyte is listed in Table 1 and instrument and reagent used to value assignment analyte is listed in Table 2.

Table 1: MANUFACTURING TARGETS*

Analyte	Level A	Level B	Level C	Level D	Level E
Albumin	As measured	As measured	As measured	As measured	As measured
Bicarbonate (mmol/L)	10 ± 1	17.5 ± 1.75	25 ± 2.5	32.5 ± 3.25	40 ± 4
Bili, Total (mg/dL)	As measured	5 ± 2	10 ± 2	15 ± 2	20 ± 2
Bili, Conj. (mg/dL)	As measured	2.5 ± 0.25	5 ± 0.5	7.5 ± 0.75	10 ± 1
Calcium (mg/dL)	1.5 ± 0.2	5.2 ± 0.5	8.8 ± 0.9	12.4 ± 1	16 ± 1.6
Chloride (mmol/L)	50 ± 5	82 ± 8.5	113 ± 11.3	144 ± 14.5	175 ± 17.5
Cholesterol (mg/dL)	2 ± 1	125 ± 15	250 ± 25	375 ± 38	500 ± 50
HDL-Chol (mg/dL)	1 ± 1	37.5± 5	75 ± 8	112 ± 15	150 ± 15
Creatinine (mg/dL)	0.2 ± 0.1	6.3 ± 0.7	12.5 ± 1.25	18.8 ± 1.9	25 ± 2.5
Glucose (mg/dL)	7 ± 1	200 ± 20	394 ± 40	587 ± 59	780 ± 78
Iron (µg/dL)	As measured	144 ± 15	288 ± 30	432 ± 45	576 ± 58
Lactic Acid (mmol/L)	0.5 ± 0.1	3.25 ± 0.4	6 ± 0.6	9 ± 0.9	12 ± 1.2
Magnesium (mg/dL)	2 ± 0.2	2.8 ± 0.3	3.5 ± 0.4	4.25 ± 0.4	5 ± 0.5
Osmolality	As measured	As measured	As measured	As measured	As measured
Phosphorus (mg/dL)	1 ± 0.5	2.8 ± 0.3	4.5 ± 4.5	6.3 ± 0.7	8 ± 0.8
Potassium (mEq/dL)	1 ± 0.5	4 ± 0.8	7 ± 0.9	10 ± 1	13 ± 1.3
Protein, Total (g/dL)	2 ± 0.3	4.3 ± 0.5	6.5 ± 0.7	9 ± 0.9	11 ± 1.1
Sodium (mmol/L)	80 ± 8	103 ± 11	125 ± 13	148 ± 15	170 ± 17
Triglycerides (mg/dL)	1 ± 0.5	220 ± 22	439 ± 44	658 ± 66	876 ± 88
Uric Acid (mg/dL)	0.5 ± 0.2	5.4 ± 0.7	10.3 ± 1.1	15.2 ± 1.6	20 ± 2
Urea Nitrogen (mg/dL)	0.5 ± 0.2	32 ± 3.5	62.5 ± 6.5	94 ± 9.5	125 ± 8
A. Phosphatase (IU/L)	4 ± 2	27 ± 4	50 ± 6	73 ± 7.8	95 ± 9.5
ALT/GPT (IU/L)	3 ± 1	240 ± 24	477 ± 48	714 ± 72	950 ± 95
ALP (IU/L)	3 ± 2	303 ± 31	602 ± 61	901 ± 91	1200 ± 120
AMY (IU/L)	2 ± 1	502 ± 50	1001 ± 100	1501 ± 150	2000 ± 200
CK (IU/L)	3 ± 1	503 ± 51	1002 ± 101	1501 ± 150	2000 ± 200
AST/GOT (IU/L)	3 ± 1	240 ± 24	477 ± 48	714 ± 72	950 ± 95
χ GT (IU/L)	2 ± 1	339 ± 34	676 ± 68	1013 ± 101	1350 ± 135
LDH (IU/L)	2 ± 1	239 ± 24	476 ± 48	713 ± 72	950 ± 95
LIPASE (IU/L)	2 ± 1	77 ± 8	151 ± 15	226 ± 23	300 ± 30
LDL Chol (mg/dL)	1 ± 0.5	101 ± 11	201 ± 21	301 ± 31	400 ± 40

*The manufacturing targets are based on the performance of the listed instrument and reagent that correspond to the listed analyte.

Value Assignment Protocol: To obtain the target values for each analyte listed in table 2, Aalto Scientific, Ltd. will perform Value Assignment according to Aalto's SOP Q-0051, titled "Value Assignment Protocol for Aalto Label Control". Protocol is to collect 30 values for each analyte listed on the instrument listed by the reagent listed. The SOP calls for three instruments or labs (if available). Ten individual assays from single evaluated vial (bottle). Require that one bottle be assayed in the morning and another in afternoon over five days time span. The thirty data points will be compiled and the average used as the target value.

Table 2: The Instrument and Reagent used for Value Assigning Analytes in Table 1.

Analyte*	Instrument	Reagents Vendor
pH	Orion	Beckman Coulter, Inc
Acid Phosphatase	Hitachi 911	Roche Diagnostic Corp
Albumin	Hitachi 911	Roche Diagnostic Corp
ALP	Hitachi 911	Thermo Trace, Ltd.
ALT/GPT	Hitachi 911	Thermo Trace, Ltd.
AMY	Hitachi 911	Thermo Trace, Ltd.
AST/GOT	Hitachi 911	Thermo Trace, Ltd.
Bicarbonate	Cobas bio	Thermo Trace, Ltd.
Bilirubin, Conjugate	Cobas bio	Hemagen Diagnostics, Inc. (Raichem)
Bilirubin, Total	Hitachi 911	Pointe Scientific, Inc.
Calcium	Hitachi 911	Pointe Scientific, Inc.
Chloride	Hitachi 911	Roche Diagnostic Corp
Cholesterol	Hitachi 911	Thermo Trace, Ltd.
CK	Hitachi 911	Pointe Scientific, Inc.
Creatinine	Hitachi 911	Roche Diagnostic Corp
Gamma GT	Hitachi 911	Roche Diagnostic Corp
Glucose	Hitachi 911	Roche Diagnostic Corp
HDL cholesterol	Hitachi 911	Roche Diagnostic Corp
Iron	Hitachi 911	Roche Diagnostic Corp
Lactic Acid	Hitachi 911	Pointe Scientific, Inc.
LDH	Hitachi 911	Thermo Trace, Ltd.
LDL cholesterol	Hitachi 911	Roche Diagnostic Corp
Lipase	Hitachi 911	Roche Diagnostic Corp
Magnesium	Cobas bio	Pointe Scientific, Inc.
Osmolality	Wescor	Wescor
Phosphorus	Hitachi 911	Roche Diagnostic Corp
Potassium	Hitachi 911	Roche Diagnostic Corp
Protein, Total	Hitachi 911	Pointe Scientific, Inc.
Sodium	Hitachi 911	Roche Diagnostic Corp

Triglycerides	Hitachi 911	Thermo Trace, Ltd.
Urea Nitrogen	Hitachi 911	Roche Diagnostic Corp
Uric Acid	Hitachi 911	Roche Diagnostic Corp
*Not all analytes tested are claimed. Aalto Scientific, Ltd. presented a complete list of QA/QC testing. Aalto Scientific, Ltd. also performs Microbial growth, Moisture and Turbidity plus an abbreviated stressed shelf life and open bottle check on each lot.		

Check Linearity: The target values will be plotted against X-axis value called level 1, 2, 3, 4, and 5 and then determine that the coefficient of correlation (R^2) greater or equal to 0.975 and if so, declare that linear relationship of the five levels has been confirmed.

Traceability (controls, calibrators, or methods): The reagents, calibrators and controls used were those purchased from the manufacturer. The instrumentations used were the Roche Diagnostic Corp Hitachi 911, Roche Diagnostic Corp Cobas Bio, Wescor 5500 Osmometer and Orion 720A pH meter. An independent control was included in each assay batch and is monitored under Aalto Scientific, Ltd. QA SOP protocols.

Stability: The stability characteristics of Audit™ Micro*CV*™ General Chemistry Linearity Set is determined using stress stability studies (stressed at 37° C) to estimate product storage stability at 2 to 8° C by linear regression and modified Arrhenus equations. The following assumption was made: if 90 to 110% of the concentration and/or activity of the listed constituent is retained when compared to a reference vial (zero day) of the same lot stored at 2 to 8° C and tested in the same a run that constituent is considered to be stable for the corresponding real time period at 2 to 8° C.

There are five levels in the General Chemistry Linearity Set, Level "A" though "E". The Level "A" concentration is set at the lowest concentration measurable by the assay and Level "E" is set at the highest concentration measurable. All other levels are merely dilutions of these two levels. After each of the five levels of Audit™ Micro*CV*™ General Chemistry Linearity Set was filled, freeze/dried and labeled, vials were placed at 2 to 8° C for storage. The stress stability study was a backward performed study were selected vials (Level A and Level E) where removed from storage at different time intervals and placed in a 37° C incubator. On the day of testing, all the vials were removed from the incubator and move vials removed from storage (zero day) and all vials were tested in the same assay with QC control material according to manufacturer instructions.

For the Open Bottle Study, "TEST" vials were reconstituted with the diluents and not re-frozen. The reconstituted vials were stored at 2 to 8 ° C. The product is removed each working day from the refrigerator and open to the

atmosphere from 10 to 60 minutes. On specified days, testing performed for all the analytes listed according to instrument and reagents specifications for their respective analyte.

The "Calculated Months to Failure" values were derived using linear regression analysis to estimate failure at less than 90% (-10%) or greater than 110% (+10%) of original recovery of each constituent for each level. Based on these failure estimates from the stress stability data, the predicted storage stability of the product of Unopened Vial at 2 to 8 ° C equals 12 years, and Open Vial at 2 to 8 ° C equals 24 hours.

Name/place of manufacturer, packer, or distributor

Manufacturer is Aalto Scientific, Ltd.
1959 Kellogg Ave
Carlsbad, CA
92008

Distributor is Audit MicroControls, Inc.
3540 W. Sahara Ave., #086
Las Vegas, NV
89102-5833

Date of last labeling revision

Date: N/A

Conclusion:

The submitted material in this premarket notification for Audit™ Micro*CV*™ General Chemistry Linearity Set supports a substantially equivalence decision based on the performance/stability and stress stability data. Real time stability data is be collected.

Attachments

Summary of Safety and Effectiveness in the format specified under 21 CFR 807.92 or 510(k)
Statement in the content and format specified under 21 CFR 807.93
Truthful and Accurate Statement
Indications for Use Form

[1]A discussion of the performance data that was generated in support of the device including protocols, raw data points, graphical representation, and analyses or conclusions for the following parameters as applicable.

[2]Provide a copy of the labeling in draft. Labeling should be conformance to the format and order of 21 CFR 809.10(b) (see below). An explanation should be provided for each element that is either absent or not applicable. 21 CFR § 809.10 Labeling for In Vitro Diagnostic Devices. 21 CFR § 809.10(b) - labeling accompanying each product (package insert) shall bear...in the format and order specified below except where not applicable:

AUDIT™
MicroControls

Audit™ MicroCV™ General Chemistry Linearity Set

Cat. No. **K701M-5**
Contents 5 x 5 mL plus diluent

Lot No. xxxxx, xxxxx, xxxxx, xxxxx, xxxxx

Expires xx/xx/xx

For In Vitro Diagnostic Use Only.

INTENDED USE

Audit™ MicroCV™ General Chemistry Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, Lactate, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments[1].

This product may also be used as unassayed quality control material for these analytes or as an assayed quality control material for the analyzer systems specified in this package insert. It is not intended to be used as an assayed quality control material for any other analyzer systems. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. In addition, it may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification[2] for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations[3].

SUMMARY AND PRINCIPLE

As defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC), each laboratory must revalidate each test method's analytical measurement range (AMR) at least every six months as well as following changes in lots of analytically critical reagents or major system components[4]. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit™ MicroCV™ General Chemistry Linearity Set may be used as one would use human serum to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

This product contains less than 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Audit™ MicroCV™ General Chemistry Linearity Set is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit™ MicroControls, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

Audit™ MicroCV™ General Chemistry Linearity Set is stored at 2-8°C and will remain stable in the unopened vial for twelve months from the date of manufacture. After opening, the contents should be reconstituted immediately and used according to the instrument manufacturer's instructions.

It is recommended that Audit™ MicroCV™ General Chemistry Linearity Set be used within twenty-four (24) hours after reconstitution and stored tightly capped at 2-8°C. Leaving the vial uncapped, or prolonging its time at room temperature, will void this reconstituted stability claim. Make sure the contents of the vial are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for quality control and for verifying and validating the AMR. Verify that the lot number on each vial matches the package insert. To avoid evaporation, do not leave the vial uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. CLIA directed calibration verification linearity material should be run[4]:

1. every six (6) months.
2. when a complete change of reagents for a procedure is introduced.
3. when there is major preventive maintenance or replacement of critical parts that may influence test performance.
4. when control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits.
5. when the laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Materials provided

- Audit™ MicroCV™ General Chemistry Linearity Set, 5 x 5 mL
- Diluent, 5 x 5 mL

INSTRUCTIONS FOR USE

1. Remove a vial from the package, reconstitute with 5ml of the diluent provided, and gently swirl occasionally for 10 minutes. Do not shake. Do not mix mechanically.

2. Refer to instrument or assay instruction manual for quality control or verifying and validating the AMR.

3. After sampling, replace stopper and return to original package at 2-8°C to obtain the maximum 24-hour reconstituted stability.

CALCULATIONS OF RESULTS

Each set of Audit™ MicroCV™ General Chemistry Linearity Set is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the NCCLS recommendation[2] for preparing linearity sets.

LIMITATIONS OF THE PROCEDURE

Make sure that each vial is brought to room temperature before testing. If the contents of any of the vials become frozen, discard all vials and request a replacement set, as the results will not be valid. If the diluent becomes cloudy, do not use as bacterial contamination may be suspected.

[2]Federal Register 42 CFR Part 493, Department of Health and Human Services. January 24, 2003; p.3691.

[3]Federal Register 42 CFR Part 493, Department of Health and Human Services. January 24, 2003; §493.2

[4]Federal Register 42 CFR Part 493, Department of Health and Human Services. January 24, 2003, §493.1255, (b) (1) (ii).

[1]Dilution schemes are based on guidelines provided by The National Committee for Clinical Laboratory Standards (NCCLS) in approved guideline EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline", April 2003.

EXPECTED VALUES

Each lot of product is manufactured such that a linear relationship exists among levels. The analyte concentrations in this insert were derived from multiple replicate analyses on the instruments indicated. Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument/reagent system calibration. The degree of acceptable non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

The material and information presented here in no manner constitutes an overruling of any federal, state or other regulatory body's regulations and/or guidelines.

ORDERING INFORMATION

Product Number	Product Description	Product Packaging
K701M-5	Audit™ Micro*CV*™ General Chemistry Linearity Set	5 x 5 mL

Analytes include:

			A*		B		C		D		E	
	Instrument	Units	mean	range	mean	range	mean	range	mean	range	mean	range
Acid Phosphatase, Total	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Albumin	Hitachi 911	g/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Alkaline Phosphatase	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
ALT	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Amylase	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
AST	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Bilirubin, Direct	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Bilirubin, Total	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Calcium	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
CO_2	Hitachi 911	mEq/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Chloride	Hitachi 911	mEq/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Cholesterol	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Creatine Kinase	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Creatinine	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Gamma-GT	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Glucose	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
HDL Cholesterol	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Iron, Total	Hitachi 911	ug/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Lactate	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
LDH	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
LDL Cholesterol	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Lipase	Hitachi 911	IU/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Magnesium	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Phosphorus	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Potassium	Hitachi 911	mEq/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Sodium	Hitachi 911	mEq/L	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Total Protein	Hitachi 911	g/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Triglycerides	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Urea (BUN)	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x
Uric Acid	Hitachi 911	mg/dL	x	x -x	x	x -x	x	x -x	x	x -x	x	x -x

*AUDIT MicroControls, Inc. does not recommend using Level A for quality control purposes as the levels may be too low to measure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Alan J. Vekich
Scientist
Aalto Scientific, Ltd.
1959 Kellogg Avenue
Carlsbad, CA 92008

DEC - 9 2004

Re: k042318
Trade/Device Name: Audit™ MicroCV™ General Chemistry Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: November 22, 2004
Received: November 22, 2004

Dear Mr. Vekich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042318

Device Name: Audit™ MicroCV™ General Chemistry Linearity Set

Indications For Use:

The Audit™ Micro*CV*™ General Chemistry Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments.

This product may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations.

In addition, levels B - E of this product may be used as unassayed quality control material for these analytes or as an assayed quality control material for the analyzer systems specified in the package insert. It is not intended to be used as an assayed quality control material for any other analyzer systems.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042318